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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,429	05/22/2000	Jeffery A. Konecke	1002-111	2363

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/575,429

Applicant(s)

KONECKE, JEFFERY A.

Examiner

Lyle A Alexander

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) see 892.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

No PTO-1449 cited, only the patent NO.'s were cited in paper 2. These patents have been cited in the 892.

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***Claim Rejections - 35 USC § 112***

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite as to what structure is intended by a "float" that will prevent splashing during sample application.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,4-8,10 and 16 are rejected under 35 U.S.C. 102(b,e) as being clearly anticipated by WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) respectively.

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WO'97 teaches a test kit for the detection of common drugs of abuse that can be detected in urine samples. WO'97 teaches in figure 1 a transparent container(11), a sealed card(25) and slit means(19) to fit the container and the card. The container(11) has been read on the claimed "specimen cup", the sealed card(25) on the claimed "cassette" and the slit means(19) on the claimed "custom fit".

Similarly, Lapp teaches a drug detection kit with a collection cup(10), a test card(22) and in figure 2 the card(22) is attached to the lid(18) of the cup(10). The cup(10) has been read on the claimed "specimen cup", the card(22) on the claimed "cassette" and the attachment of the card(22) to the lid(18) on the claimed "custom fit".

With respect to claim 10, in light of the 35 USC 112 issues above, the means to prevent splashing have been read on the side walls of the container(11) and cup(10).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over in view of WO 97/33519 (referenced as WO'97 hereafter) and Lapp(USP 5,916,815) further in view of Davis (USP 5,119,830).

See WO 97/33519 (referenced as WO'97 hereafter) and Lapp(USP 5,916,815) *supra*.

WO 97/33519 (referenced as WO'97 hereafter) and Lapp(USP 5,916,815) are silent to the claimed sloping of the floor of the testing device to channel the sample to the test cards.

Davis teaches sloping of the floor(34) to direct the fluid to the desired location. Sloping is a very effective means for fluid control. It is inexpensive to manufacture, simple and minimizes the chance of clogging when compared to other means of fluid control, such as conduits.

It would have been within the skill of the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) in view of Davis and slope the floor of the containers to direct the fluid towards the test cards to gain the above advantages.

WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) in view of Davis is silent to the claimed 1-3' of slope.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well-known results. The degree of slop of the floor would have been a result effective variable to achieve the expected and well-known results speed of fluid travel and fluid pool depth created by the slope. It would have been within the skill of

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the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) in view of Davis and use a 1-3' slope as optimization of a result effective variable.

Claims 2-3,9 and 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) in view of Davis.

See WO 97/33519 (referenced as WO'97 hereafter) and Lapp(USP 5,916,815) supra.

These references are silent to the claimed slope of the container, the retracted flat face, a one-way flap to prevent spillage of the fluid, and the claimed polymer.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well-known results.

The degree of slop of the floor would have been a result effective variable to achieve the expected and well-known results speed of fluid travel and fluid pool depth created by the slope.

The orientation of the viewing face would have been a result effective variable to achieve the well-known and predictable results of bringing the results closer to permit better viewing by people with poor eye sight.

The use of a one-way valve is convention in the art of testing to prevent escape of test substance, which is potentially hazardous. Implementation of a one-way valve

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would have been a result effective variable to gain the well-known and expected advantage of preventing the sample from contacting the technician.

It would have been within the skill of the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) and use a 1-3' slope, a flat retracted face to bring the results closer to the viewer and use of a one-way valve as optimization of result effective variables.

The court decide In re Leshin (125 USPQ 416) that selection of a plastic based upon its suitability of intended use would have been within the skill of the art.

All of the claimed plastics are notoriously well known in the art and have the advantages of inertness, durability, lightweight, ability to be recycled and low cost of manufacture. It would have been within the skill of the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) and use the claimed plastic in view of Leshin above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-305-3599 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.



Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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February 22, 2002